

In re application of
Downes et al.
Application No.: 10/658,115
Page 8

Atty. Dkt. No. SALK3130-1 (088802-9702)

REMARKS

The present invention relates to compounds which have been identified as potent farnesoid X receptor (FXR) activators. The invention also relates to methods for use of invention compounds.

By the present communication, claims 1 and 10 have been amended to define Applicants' invention with greater particularity. No new matter is introduced by the subject amendments as the amended claim language is fully supported by the specification and original claims. Specifically, claim 1 has been amended to include the feature from dependent claim 10 as originally filed. In addition, the substituted alkenyl, $-\text{CH}=\text{CH}-\text{C}(\text{O})\text{O}-t\text{-Bu}$, is expressly disclosed in the specification, see, for example, compound 105 in Figure 16.

In addition, by the present communication, claims 33-35 have been cancelled without prejudice, subject to Applicants' right to pursue these claims in a subsequent filing.

Upon entry of the amendments submitted herewith, claims 1-32 and 36-37 will remain pending. The present status of all claims in the application, and current amendments thereto, are provided in the Listing of Claims presented herein beginning on page 2.

Rejection Under 35 U.S.C. § 112, Second Paragraph

The rejection of Claims 9 and 33-35 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite is respectfully traversed.

With respect to claim 9, during a telephone discussion with the Examiner on December 13, 2005, it was clarified that claim 10 should have been rejected under 35 U.S.C. § 112, second paragraph, instead of claim 9. Accordingly, rejection of claim 9 is improper and should be withdrawn.

DLMR_278693.1

In re application of
Downes et al.
Application No.: 10/658,115
Page 9

Atty. Dkt. No. SALK3130-1 (088802-9702)

With respect to a rejection of claim 10 under 35 U.S.C. § 112, second paragraph, the rejection is respectfully traversed. By the present communication, claim 1 has been amended to define the substituent R^3 to include $-\text{CH}=\text{CH}-\text{C}(\text{O})\text{O}-t\text{-Bu}$. This feature was included in original claim 10, and is expressly contemplated by the specification, see, for example, compound 105 of Figure 16. In conjunction with the amendment to claim 1, claim 10 has been amended to depend from claim 1. Thus, as presently amended, claim 10 clearly indicates what is regarded as the invention. Rejection of claim 10 is therefore improper and should be withdrawn.

With respect to the rejection of claims 33-35, the rejection is respectfully traversed. Applicants respectfully disagree with the Examiner's assertion that the claim(s) are allegedly indefinite and fail to particularly point out and distinctly claim the subject matter regarded as the invention (Office Action, page 2). Contrary to the Examiner's assertion, it is respectfully submitted that exemplary processes contemplated for modulation according to the invention are provided at paragraph [0091], and include, *inter alia*, cholesterol metabolism and the regulation of lipid homeostasis.

However, in order to reduce the issues and expedite prosecution, this rejection has been rendered moot by the cancellation of claims 33 - 35. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 112, second paragraph.

Rejection Under 35 U.S.C. § 112, First Paragraph

The rejection of Claims 33-35 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement is respectfully traversed. Applicants respectfully disagree with the Examiner's assertion that the claim(s) allegedly contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention (Office Action, page 2).

DLMR_278693.1

In re application of
Downes et al.
Application No.: 10/658,115
Page 10

Atty. Dkt. No. SALK3130-1 (088802-9702)

Contrary to the Examiner's assertion, it is respectfully submitted that invention methods are described in such a way as to enable one skilled in the art to make and/or use the invention. FXR mediated processes, such as cholesterol metabolism and lipid homeostasis are described in the specification, see, for example, paragraphs [0090] – [0091]. The step of administering an effective amount of at least one compound of the invention to a subject in need thereof is readily understood by those of skill in the art.

However, in order to reduce the issues and expedite prosecution, this rejection has been rendered moot by the cancellation of claims 33-35. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 112, first paragraph.

In view of the above amendments and remarks, reconsideration and favorable action on all claims are respectfully requested. In the event any issues remain to be resolved in view of this communication, the Examiner is invited to contact the undersigned by telephone so that a prompt disposition of this application can be achieved.

Respectfully submitted,

Date

1/19/06

By



FOLEY & LARDNER LLP
Customer Number: 30542
Telephone: (858) 847-6711
Facsimile: (858) 792-6773

Stephen E. Reiter
Attorney for Applicant
Registration No. 31,192

DLMR_278893.1